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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,936	01/07/2004	James Loyd	930027-2022	5800
20999	7590	11/30/2005		
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER DIXON, ANNETTE FREDRICKA	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/752,936	Applicant(s) LOYD ET AL.	
	Examiner Annette Dixon	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/23/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of **Claims 1 through 21** in response to phone call placed by Mr. Henry Bennett, Supervisor of Art Unit 3743, to Mr. Ronald Santucci of Frommer, Lawrence, & Haug on Wednesday, November 9, 2005, at 1:45 P.M is acknowledged.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21 are drawn to an Endotracheal Tube Apparatus, classified in class 128, subclass 207.140.
 - II. Claims 22-25 are drawn to a Method of Implanting an Endotracheal Tube classified in class 128, subclass 898.
2. The inventions are distinct, each from the other because:

Inventions Group I, Endotracheal Tube Apparatus, and Group II, Method of Implanting an Endotracheal Tube, are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed in Group I can practice a material different methods in that first and second flanges could be used to form a support for implanting an endotracheal tube.

Art Unit: 3743

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) were not mentioned in the description: Item 22 and Item 28. Items 22 and 28 were not listed in the specification; therefore, the features possessed by these items could not be analyzed. In addition, the drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "second flange compris[ing] a first and a second thickness, said second thickness portion being smaller than the first and being sufficiently flexible to assist in the implantation of the apparatus (**Claims 4 and 15**).” The aforementioned informalities must be shown or the feature(s) canceled from the claim(s). Please correct the to show the multiple thicknesses of the second flange (Item 14) discussed in **Claims 4 and 15**. Finally, the drawings are objected to because Figures 3, 4, and 5, fail to reflect the location of the first flange

Art Unit: 3743

(Item 12). Please correct Figures 3, 4, and 5 to show the accurate location of the first flange (Item 12).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because of the following informality: on Page 7, Line 18 the word stent is spelled "sent".

Appropriate correction is required.

Please correct the misspelling.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1, 5, 8, 9, 12, 18, and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Muto (US Patent 4246897).

Regarding **Claims 1, 5, and 12**, Muto discloses a Tracheotomy Obturator and Tube Flange consisting of a cap with air passages (48), a wing shaped collar or flange (32), a tracheotomy tube or shaft (21), and an elongated conduit or catheter (55). The air passages are open to the air and thus act as an oxygen supply line to the patient. Regarding **Claims 8, 9, 18, and 19**, Muto discloses “the tip (59) of conduit (55) and the surface (53) of tapered plug (45) are blunt and of soft material so that they are not sharp and likely to damage the trachea” (Please see Column 3, Line 37-39).

9. **Claims 1, 5, 6, 8, 12, 16, and 18** are rejected under 35 U.S.C. 102(b) as being anticipated by Linder (US Patent 5251617).

Art Unit: 3743

Regarding **Claims 1, 5, and 12**, Linder discloses an Endotracheal Tube with Concentrically Mounted and Axially Slidable Connector consisting of an external first flange (36), an internally stepped hollow, cylindrical output section (56), which functions as a second flange, a hollow output section (33), and a catheter (40). The endotracheal tube is open to the air and thus act as an oxygen supply line to the patient. Regarding **Claims 6, and 16**, Linder discloses, "within bore (34), near the center of the central flange (36), a stop is formed by the shoulder separating the bores (34) and (35), since the diameter of bore (35) is always less than the diameter of bore (34). This stop prevents the removal of connector (31) from the flanged, proximal tip (43) of catheter (40)" (Please see Column 4, Line 62 to Column 5, Line 2). Regarding **Claims 8 and 18**, Linder discloses, "the small amount of bending of proximal end portion (41) of catheter (40) within bore (60) minimizes any likelihood of occluding the lumen of catheter (40)" (Please see Column 4, Lines 45 thru 48).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3743

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 2, 3, 13, and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto and Linder in view of Sheridan (US Patent 3973569).

Regarding **Claims 2 and 13**, "wherein the first and second flange are offset 90 degrees from one another." These claims are inherently broad and disclose no physical geometry. Therefore, using the broadest reasonable interpretation of **Claims 2 and 13** one can infer that the applicant could be discussing the faces of each flange are inherently offset by 90 degrees. Both Muto and Linder are discussed above, yet both references fail to teach the concept of the flanges or flange faces being offset by 90 degrees. Sheridan discloses a dual flange surgical device formed of flexible, non fibrous plastic (10 and 22). Sheridan device comprises "a fixed flange member (10), a slideable [/rotatable] flange member (22), and a plurality of slideable and separately removable ring members (40) positioned between the fixed and slideable flange member" (Please see the abstract). Further Sheridan states, "the second flange member (22) slideably [/rotatably] encircles the tubular section (8)" (Please see Column 2, Lines 44 and 45). Note that this arrangement would enable the flange (22) to be rotated 90 degrees relative to flange (10). Also Sheridan states, "In special cases requiring the greatest depth of insertion, all the ring members (40) as well as the second flange member (22) can be removed leaving only the fixed flange member (10)" (Please see column 3, lines 29-33). In view of the teachings of Sheridan, it would have been

obvious to one having ordinary skill in the art at the time of the invention to modify Muto and/or Linder to include flange members whose faces and physical geometry are capable of being offset by 90 degrees via the encircling movement around the tubular section of the slideable flange members to aide in the removal and placement of the flanges on the tubular section (8). Regarding **Claims 3 and 14**, Muto and Linder are discussed above, yet fail to disclose holes formed in the first flange for affixing the apparatus to the patient. Sheridan discloses slots (18 and 20) in the first flange member (10) as well as slots (30 and 32) on the second flange member (22). Sheridan states, "the flange members have end slots to receive tie tape and the flanges and ring members have aligned holes to provide connection means" (Please see column 2, lines 5-7). However, when the second flange (22) and the rings between the first and second flange (40) are removed, the device contains only one flange with slots that can be used attach the flange to the patient (Please see column 3, lines 29-33). In view of the teaching of Sheridan, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Muto and/or Linder to include a end slots located on the flange to provide a connection means and to assist in retaining and maintaining the position of the tracheotomy tube.

12. **Claims 4 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto and Linder in view of Tabor (US Patent 4325366). Muto and Linder are discussed above; yet fail to teach the second flange comprising a first and second thickness. Tabor discloses a dual flange (24 and 18) device that is capable of being

Art Unit: 3743

used with a tracheotomy tube. The base (10) of the second flange (18) "is made of a pliable plastic material such as silicone in order that tubular portion (16) may easily receive valve body (12) inserted into it and flanged portion (18) may easily conform to the paratracheal skin of the patient. A portion (20) of flange (18) can be tapered to facilitate flange (18) conforming to the skin of the patient" (Please see column 2, lines 27-33). The flexibility of the second flange in addition to the second flange's tapered geometry addresses the limitations recited in **Claims 4 and 15**. In view of the teachings from Tabor, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Muto and/or Linder to include a tapered flange to provide a surface where the body of the patient can conform to resulting in a comfortable and tight seal.

13. **Claims 7 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto and Linder in view of Arkinstall (US Patent 5287852). Muto and Linder are discussed above; yet fail to teach the concept of adding a bushing or washer larger in diameter than the lumen. Arkinstall discloses a tracheal apparatus that contains a bushing conduit (12) and a washer (14). The washer "enables the wall to be squeezed over a continuous range of forces which enables the apparatus to be installed securely, yet comfortably on the tracheostomy patient" (Please see column 3, line 55 –59). The bushing conduit (12) is "removably secured to the patient's neck. The unobstructed coterminous opening in the conduit permit the insertion of a cuffed endotracheal tube to provide an airtight seal in the trachea to allow for mechanical ventilation, allows easy

Art Unit: 3743

access of suction catheter to clear retained secretions, and enables a plug or other device to seal the ventilation opening to allow for near normal ventilation to and from the trachea via the oropharynx , with out compromising the engagement of the retaining means with the anterior tracheal wall and with out appreciably compromising air flow the trachea" (Please see column 4, line 3-14). In view of the teachings of Arkinstall, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Muto and/or Linder to include a bushing where in the diameter of the bushing is larger than that of the lumen to provide a method of maintaining the tracheal stoma with out compromising the patient's air flow.

14. **Claims 10 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto and Linder in view of Miller (US Patent 3659611) and further in view of Kolobow (US Patent 5305740). Muto and Linder are discussed above, yet fail to teach the first and second flanges being opposedly curved. Miller discloses a tracheal tube seal consisting of "a series of thin, solid, resilient, disc-like flanges (18, 19, and 20) preferably attached to the tubular potion (12) in spaced parallel relationships perpendicular to the axis of the tubular portion" (Please see column 2, lines 13-16). Seen below is figure 2 of the Miller patent showing the device inserted into the patient.

Patented May 2, 1973

3,659,611

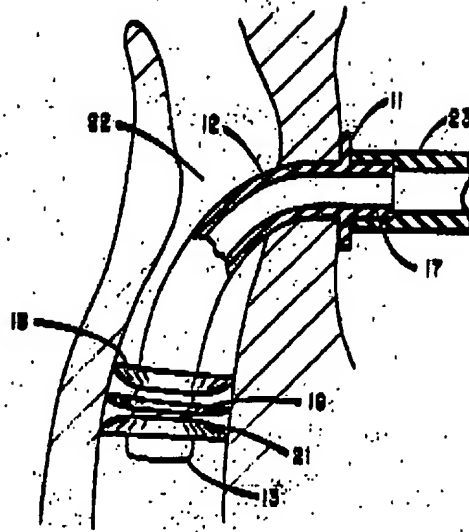


Fig. 2

As seen above, the flanges (18 and 21) have become opposedly curved as a result of the flexible nature of the material used to create the flanges and insertion into the patient's trachea. Regarding the middle flange (19), Miller teaches that a choice when designing the number of flanges that are incorporated into a tracheal device. (Please see column 2, lines 32-33). It would have been obvious to one having ordinary skill in the art to modify the tracheal system of Muto and Linder to have provided a dual or multiple flange system for the purpose of creating a tight seal between the tracheal device and the patient's trachea.

The combination of Muto and Linder as modified by Miller; however, does not show or teach an insertion method for creating the opposedly curved flanges from multi-flanged systems. Kolobow teaches a sealing means for endotracheal tubes incorporating multiple flange system using flanges (53) with tapered edges as seen in

below in figure 6B of the Kolobow patent. Kolobow states "when the tubular member having curved gills or flanges (53) is first inserted then backed out a short distance to reverse the curve of the gills or flanges (53) from the direction in which they are oriented when being inserted. In this embodiment, the curve shape can provide a small bias force to the seal means" (Please see column 9, line 17-21). It would have been obvious

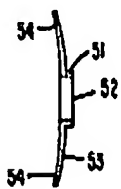


FIG. 6B

to one of ordinary skill in the art to have modified the tracheal system of Muto and Linder as modified by Miller to have provided an insertion method for creating the opposedly curved flanges from multi-flanged systems as taught by Kolobow for the purpose of creating a tight seal

between the tracheal device and the patient's trachea.

15. **Claims 11 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto and Linder in view of Thomas (US Patent Publication: US 2005/0166924 A1). Muto and Linder are discussed above; yet fail to teach the concept of the flanges having different values of durometer hardness. Thomas discloses a multiple cannula system for a tracheostomy tube assembly. The cannula system where, "the substantially rigid tip potion being made with a rigid PVC material having a shore D hardness of between 55 to 65 and the substantially flexible portion being made with a flexible PVC material having a shore A hardness of between 80 to 90" (Please see paragraph 11). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the tracheal system of Muto and Linder to have incorporated structural elements at different hardness values as taught by Thomas for the purpose of providing

Art Unit: 3743

the necessary level of durability for structures that are exposed to different environmental forces and elements.

The specific hardness values are noted; however, from a close reading of the specification there is no criticality disclosed for the actual hardness values of about 70 for the first flange and of about 50 for the second flange. Therefore, one of ordinary skill in the art at the time of the invention would find it obvious to construct the flanges to the claimed hardness values or any other hardness values that are suitable to the procedure that is being administered on the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette Dixon whose telephone number is (571)272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

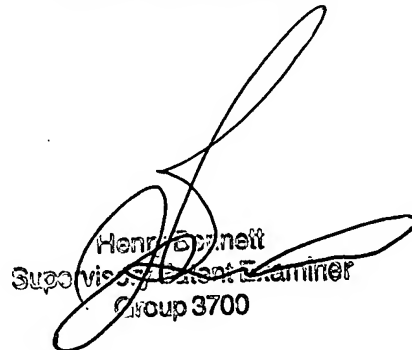
Art Unit: 3743

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Annette Dixon
Examiner
Art Unit 3743
November 22, 2005

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